

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

IN RE:

BRIMONIDINE PATENT LITIGATION

MDL Docket No. 07-md-01866 GMS

## JOINT CLAIM CHARTS

'078 patent<sup>1</sup>

Asserted Claim of '078 patent	Allergan's Proposed Construction <sup>2</sup>	Apotex's Proposed Construction
<b>Claim 1</b>		
1. A method for preserving an aqueous ophthalmic formulation so as to enhance the shelf life thereof comprising	Agreed-upon construction: The claim requires a method for preserving an aqueous ophthalmic formulation to enhance the shelf life of the formulation.	
incorporating into said aqueous ophthalmic formulation stabilized chlorine dioxide in an amount effective to act as the sole preservative in said aqueous ophthalmic formulation,	The claimed method requires incorporation into the aqueous ophthalmic formulation of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the formulation.	The claimed method requires incorporation into the aqueous ophthalmic formulation of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the formulation.
		<b>"stabilized chlorine dioxide in an amount effective to act as the sole preservative in said aqueous ophthalmic</b>

<sup>1</sup> Allergan and Apotex agree on the construction for many of the claim terms. There are, however, a few where Allergan and Apotex agree as to a portion of the construction but the remainder is in dispute. To facilitate the Court's review of this joint claim chart, where a portion of the construction of the term is in dispute but not the entire construction, the disputed portion is in bold.

<sup>2</sup> Because the claim language itself is clear and unambiguous, no resort to the specification and prosecution history is necessary, therefore, the best evidence that the plain and ordinary meaning of the claim terms controls is the claims themselves. For brevity, citation to the claim language itself will not be repeated each time as the claim language is provided in Column 1.

Asserted Claim of '078 patent	Allergan's Proposed Construction <sup>2</sup>	Apotex's Proposed Construction
	<p>See, e.g., Col. 2:35-36; 61-66; 3:13-21; and 4:1-23, Examples I-VIII; '078 Prosecution History, Amendment February 29, 1992</p>	<p><b>formulation" means an amount so that a 99.9% reduction of microbes challenge occur within 14 days of contact with the product being tested; and that no growth of yeast and fungi occur.</b></p> <p><i>See, e.g., '078 patent, column 8, lines 40-43.</i></p>
<p>at least one ophthalmically acceptable buffer component in an amount effective to maintain said aqueous ophthalmic formulation at a pH in the range of about 6.8 to about 8,</p>	<p>Agreed-upon construction: The claimed method requires incorporation into the aqueous ophthalmic formulation of at least one ophthalmically acceptable buffer component in an amount effective to maintain the formulation at a pH in the range of approximately 6.8 to approximately 8.</p>	
<p>and at least one ophthalmically acceptable tonicity component in an amount effective to maintain said aqueous ophthalmic formulation at an osmolality of at least about 200 mOsmol/kg,</p>	<p>The claimed method requires incorporation into the aqueous ophthalmic formulation of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the formulation at an osmolality of at least approximately 200 mOsmol/kg.</p> <p>Allergan disagrees with Apotex that the language "Ophthalmically acceptable tonicity component" is defined in the specification as any tonicity component or components "provided that such component or components are compatible</p>	<p>The claimed method requires incorporation into the aqueous ophthalmic formulation of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the formulation at an osmolality of at least approximately 200 mOsmol/kg.</p> <p><b>"Ophthalmically acceptable tonicity component" is defined in the specification as any tonicity component or components "provided that such component or components are compatible with the other ingredients of the ophthalmic formulation</b></p>

Asserted Claim of '078 patent	Allergan's Proposed Construction <sup>2</sup>	Apotex's Proposed Construction
	<p>with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye,” is necessary.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharmas. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '078 patent, col. 2, lines 38-42; col. 5, lines 13-44; Examples V-VIII. 078 Prosecution History, Amendment dated February 27, 1992; Appellant’s Brief dated September 18, 1992.</p>	<p><b>and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharmas. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>The limitation of “at least about 200 mOsmol/kg” is supported by the written description at column 5, lines 13-23.</p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
provided that said aqueous ophthalmic formulation is ophthalmically acceptable and no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers are incorporated into said aqueous ophthalmic formulation.	Agreed-upon construction: The claimed method requires that the aqueous ophthalmic formulation is ophthalmically acceptable and that it includes no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers.	
<b>Claim 2</b>		
2. The method of claim 1 wherein said stabilized chlorine dioxide is present in said aqueous ophthalmic formulation in an amount in	Agreed-upon construction: Claim 2 contains all the limitations of claim 1, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.0002 to approximately 0.02 weight/volume percent.	

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the range of about 0.0002 to about 0.02 weight/volume percent.		
<b>Claim 3</b>		
3. The method of claim 1 wherein said stabilized chlorine dioxide is present in said aqueous ophthalmic formulation in an amount in the range of about 0.004 to about 0.01 weight/volume percent.	Agreed-upon construction: Claim 3 includes all the limitations of claim 1, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.004 to approximately 0.01 weight/volume percent.	
<b>Claim 4</b>		
4. The method of claim 1 wherein said at least one ophthalmically acceptable buffer component is present in an amount effective to maintain said aqueous ophthalmic formulation at a pH in the range of about 7 to about 7.5.	Agreed-upon construction: Claim 4 includes all the limitations of claim 1, with the further requirement that at least one ophthalmically acceptable buffer component is present in an amount effective to maintain the formulation at a pH in the range of approximately 7 to approximately 7.5.	
<b>Claim 5</b>		
5. The method of claim 1 wherein said at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain said aqueous ophthalmic formulation at an osmolality in the range of about 200 to about 400 mOsmol/kg.	Claim 5 includes all the limitations of claim 1, with the further requirement that at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain the formulation at an osmolality in the range of approximately 200 to approximately 400 mOsmol/kg.	Claim 5 includes all the limitations of claim 1, with the further requirement that at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain the formulation at an osmolality in the range of approximately 200 to approximately 400 mOsmol/kg.
	Allergan disagrees with Apotex that the language "Ophthalmically acceptable tonicity component" is defined in the specification as any tonicity component or components "provided that such component or	<b>"Ophthalmically acceptable tonicity component" is defined in the specification as any tonicity component or components "provided that such component or components are compatible with the other ingredients of</b>

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	<p>components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye,” is necessary.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharmas. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '078 patent, col. 2, lines 38-42; col. 5, lines 13-44; Examples V-VIII.</p> <p>See citations for Claim 1 above.</p>	<p><b>the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharmas. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>The limitation of “effective to maintain the formulation at an osmolality in the range of approximately 200 to about 400 mOsmol/kg” is supported by the written description at column 5, lines 13-23.</p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
<b>Claim 6</b>		
6. The method of claim 1 wherein said aqueous ophthalmic formulation is a solution.	Agreed-upon construction: Claim 6 includes all the limitations of claim 1 with the further requirement that the aqueous ophthalmic formulation is a solution.	
<b>Claim 7</b>		
7. A method for preserving an aqueous ophthalmic solution so as to enhance the shelf life thereof comprising	Agreed-upon construction: The claim requires a method for preserving an aqueous ophthalmic solution to enhance the shelf life of the solution.	

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<p>incorporating into said aqueous ophthalmic solution stabilized chlorine dioxide in an amount effective to act as the sole preservative in said aqueous ophthalmic solution in the range of about 0.002 to about 0.02 weight/volume percent,</p>	<p>The claimed method requires incorporation into the aqueous ophthalmic solution of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the solution in the range of approximately 0.0002 to approximately 0.02 weight/volume percent.</p> <p>Allergan disagrees Apotex that the language “stabilized chlorine dioxide in an amount effective to act as the sole preservative in said aqueous ophthalmic solution” means an amount so that a 99.9% reduction of microbes challenge occur within 14 days of contact with the product being tested; and that no growth of yeast and fungi occur.” is necessary.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.,</i> col. 2, lines 35-36; 61-66; col. 3, lines 13-21; and 4:15-23; Examples I-VIII</p>	<p>The claimed method requires incorporation into the aqueous ophthalmic solution of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the solution in the range of approximately 0.0002 to approximately 0.02 weight/volume percent.</p> <p><b>"stabilized chlorine dioxide in an amount effective to act as the sole preservative in said aqueous ophthalmic solution" means an amount so that a 99.9% reduction of microbes challenge occur within 14 days of contact with the product being tested; and that no growth of yeast and fungi occur.</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>See, e.g., '078 patent, column 8, lines 40-43.</p>

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at least one ophthalmically acceptable buffer component in an amount effective to maintain said aqueous ophthalmic solution at a pH in the range of about 6.8 to about 8,	See citations for Claim 1 above.	Agreed-upon construction: The claimed method requires incorporation into the aqueous ophthalmic solution of at least one ophthalmically acceptable buffer component in an amount effective to maintain the solution at a pH in the range of approximately 6.8 to approximately 8.
and at least one ophthalmically acceptable tonicity component in an amount effective to maintain said aqueous ophthalmic solution at an osmolality in the range of about 200 to about 400 mOsmol/kg,	<p>The claimed method requires incorporation into the aqueous ophthalmic solution of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the solution at an osmolality in the range of approximately 200 mOsmol/kg to approximately 400 mOsmol/kg.</p> <p>Allergan disagrees that the language “Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye,” is necessary.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order</p>	<p>The claimed method requires incorporation into the aqueous ophthalmic solution of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the solution at an osmolality in the range of approximately 200 mOsmol/kg to approximately 400 mOsmol/kg.</p> <p><b>“Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order</p>

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	<p>No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '078 patent, Col. 2, lines 38-42; col. 5, lines 13-44; Examples V-VIII.</p> <p>See citations for Claim 1 above.</p>	<p>construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>The limitation of “an amount effective to maintain the formulation at an osmolality in the range of about 200 to about 400 mOsmol/kg” is supported by the written description at column 5, lines 13-23.</p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
<p>provided that said aqueous ophthalmic solution is ophthalmically acceptable and substantially no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers are incorporated into said aqueous ophthalmic solution.</p>	<p>Agreed-upon construction:</p> <p>The claimed method requires that the aqueous ophthalmic solution is ophthalmically acceptable and that it includes substantially no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers.</p>	
<p><b>Claim 8</b></p>		
8. A preserved ophthalmic formulation comprising	<p>Agreed-upon construction:</p> <p>The claim requires a preserved ophthalmic formulation.</p>	
an ophthalmically acceptable aqueous medium and,	<p>Agreed-upon construction:</p> <p>The claimed formulation requires an ophthalmically acceptable aqueous medium.</p>	
included therein, stabilized chlorine dioxide in an amount effective to act as the sole preservative in said ophthalmically acceptable aqueous medium,	<p>The claimed formulation requires the inclusion of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the ophthalmically acceptable aqueous medium.</p>	<p>The claimed formulation requires the inclusion of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the ophthalmically acceptable aqueous medium.</p>

Asserted Claim of '078 patent	Allergan's Proposed Construction <sup>2</sup>	Apotex's Proposed Construction
	<p><i>See, e.g., col. 2, lines 35-36; 61-66; col. 3, lines 13-21; and 4:15-23.</i></p> <p>See citations for Claim 1 above.</p>	<p><b>"stabilized chlorine dioxide in an amount effective to act as the sole preservative in said ophthalmically acceptable aqueous medium" means an amount so that a 99.9% reduction of microbes challenge occur within 14 days of contact with the product being tested; and that no growth of yeast and fungi occur.</b></p> <p>See, e.g., '078 patent, column 8, lines 40-43.</p>
<p>at least one ophthalmically acceptable buffer component in an amount effective to maintain said ophthalmically acceptable aqueous medium at a pH in the range of about 6.8 to about 8,</p>	<p>Agreed-upon construction: The claimed formulation requires the inclusion of at least one ophthalmically acceptable buffer component in an amount effective to maintain the ophthalmically acceptable aqueous medium at a pH in the range of approximately 6.8 to approximately 8.</p>	
<p>and at least one ophthalmically acceptable tonicity component in an amount effective to maintain said ophthalmically acceptable aqueous medium at an osmolality of at least about 200 mOsmol/kg,</p>	<p>The claimed formulation requires the inclusion of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the ophthalmically acceptable aqueous medium at an osmolality of at least approximately 200 mOsmol/kg.</p> <p>Allergan disagrees with</p>	<p>The claimed formulation requires the inclusion of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the ophthalmically acceptable aqueous medium at an osmolality of at least approximately 200 mOsmol/kg.</p> <p><b>"Ophthalmically acceptable</b></p>

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	<p>Apotex that the language “Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.” is necessary.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharmas. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '078 patent, col. 2, lines 20-58; col. 2, lines 61-68; col. 4, lines 1-23; col. 5, lines 13-44; Examples I-VIII.</p> <p>See citations for Claim 1 above.</p>	<p><b>tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharmas. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>The limitation of “at least about 200 mOsmol/kg” is supported by the written description at column 5, lines 13-23.</p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
provided that said preserved ophthalmic formulation is ophthalmically acceptable and is free of germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers.	<p>Agreed-upon construction:</p> <p>The claimed formulation is ophthalmically acceptable and free of germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers.</p>	

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<b>Claim 9</b>		
9. The preserved ophthalmic formulation of claim 8 wherein said stabilized chlorine dioxide is present in said preserved ophthalmic formulation in an amount in the range of about 0.0002 to about 0.02 weight/volume percent.	Agreed-upon construction: Claim 9 contains all the limitations of claim 8, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.0002 to approximately 0.02 weight/volume percent.	
<b>Claim 10</b>		
10. The preserved ophthalmic formulation of claim 8 wherein said stabilized chlorine dioxide is present in said preserved ophthalmic formulation in an amount in the range of about 0.004 to about 0.01 weight/volume percent.	Agreed-upon construction: Claim 10 contains all the limitations of claim 8, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.004 to approximately 0.01 weight/volume percent.	
<b>Claim 11</b>		
11. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component is selected from the group consisting of alkali metal chlorides and alkaline earth metal chlorides and mixtures thereof.	Claim 11 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component is selected from the group consisting of alkali metal chlorides and alkaline earth metal chlorides and mixtures thereof.	Claim 11 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component is selected from the group consisting of alkali metal chlorides and alkaline earth metal chlorides and mixtures thereof.
	Allergan disagrees with Apotex that the language "Ophthalmically acceptable tonicity component" is defined in the specification as any tonicity component or components "provided that such component or components are compatible with the other ingredients of the ophthalmic formulation	<b>"Ophthalmically acceptable tonicity component" is defined in the specification as any tonicity component or components "provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which</b>

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	<p>and do not have deleterious or toxic properties which could harm the eye.” is necessary.</p> <p><i>See., e.g.,</i> '078 patent, col. 5, lines 23-44; Examples V-VIII.</p> <p>See citations for Claim 1 above.</p>	<p><b>could harm the eye.”</b></p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
<b>Claim 12</b>		
12. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component comprises sodium chloride.	<p>Claim 12 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component comprises sodium chloride.</p> <p>See citations for Claim 1 above.</p>	<p>Claim 12 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component comprises sodium chloride.</p> <p><b>“Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
<b>Claim 13</b>		
13. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component comprises an alkaline earth metal salt selected from the group consisting of calcium chloride and magnesium chloride and	<p>Claim 13 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component comprises an alkaline earth metal salt selected from the group consisting of calcium chloride and magnesium</p>	<p>Claim 13 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component comprises an alkaline earth metal salt selected from the group consisting of calcium chloride and magnesium</p>

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mixtures thereof.	<p>chloride and mixtures thereof.</p> <p>Allergan disagrees with Apotex that the language “Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.” is necessary.</p> <p>See., e.g., '078 patent, col. 5, lines 13-44; Examples V-VIII.</p> <p>See citations for Claim 1 above.</p>	<p>chloride and mixtures thereof.</p> <p><b>“Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
<b>Claim 14</b>		
14. The preserved ophthalmic formulation of claim 8 wherein said at least one buffer component is selected from the group consisting of potassium phosphates, boric acid, sodium borate, sodium phosphates and mixtures thereof.	Agreed-upon construction: Claim 14 contains all the limitations of claim 8, with the further requirement that at least one buffer component is selected from the group consisting of potassium phosphates, boric acid, sodium borate, sodium phosphates and mixtures thereof.	
<b>Claim 15</b>		
15. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable buffer component is present in an amount effective to maintain said ophthalmically acceptable aqueous medium at a pH in the range of about 7 to about 7.5.	Agreed-upon construction: Claim 15 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable buffer component is present in an amount effective to maintain the ophthalmically acceptable aqueous medium at a pH in the range of approximately 7 to approximately 7.5.	
<b>Claim 16</b>		

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<p>16. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain said ophthalmically acceptable aqueous medium at an osmolality in the range of about 200 to about 400 mOsmol/kg.</p>	<p>Claim 16 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain the ophthalmically acceptable aqueous medium at an osmolality in the range of approximately 200 to approximately 400 mOsmol/kg.</p> <p>Allergan disagrees with Apotex that the language “Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.” is necessary.</p> <p>See, e.g., '078 patent, col. 2, lines 20-58; col. 2, lines 61-68; col. 4, lines 1-23; col. 5, lines 13-44; Examples I-VIII.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	<p>Claim 16 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain the ophthalmically acceptable aqueous medium at an osmolality in the range of approximately 200 to approximately 400 mOsmol/kg.</p> <p><b>“Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>The limitation of “an amount effective to maintain the formulation at an osmolality in the range of about 200 to</p>

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	<p>patent nos. 6,673,337 and 6,641,834).</p> <p>See citations for Claim 1 above.</p>	<p>about 400 mOsmol/kg" is supported by the written description at column 5, lines 13-23.</p> <p>The definition of "ophthalmically acceptable tonicity component" is at column 5, lines 24-33.</p>
<b>Claim 17</b>		
17. The preserved ophthalmic formulation of claim 8 which is a solution.	Agreed-upon construction: Claim 17 contains all the limitations of claim 8, with the further requirement that the formulation is a solution.	
<b>Claim 18</b>		
18. A preserved ophthalmic solution comprising	Agreed-upon construction: The claim requires a preserved ophthalmic solution.	
an ophthalmically acceptable aqueous solution and,	Agreed-upon construction: The claim requires an ophthalmically acceptable aqueous solution.	
included therein, stabilized chlorine dioxide in an amount effective to act as the sole preservative in said ophthalmically aqueous acceptable solution in the range of about 0.002 to about 0.02 weight/volume percent,	<p>The claimed solution requires the inclusion of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the ophthalmically acceptable aqueous solution in the range of approximately 0.002 to approximately 0.02 weight/volume percent.</p> <p>Allergan disagrees with Apotex that the language "stabilized chlorine dioxide in an amount effective to act as the sole preservative in said ophthalmically aqueous acceptable solution" means an amount so that a 99.9% reduction of microbes challenge occur within 14</p>	<p>The claimed solution requires the inclusion of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the ophthalmically acceptable aqueous solution in the range of approximately 0.002 to approximately 0.02 weight/volume percent.</p> <p><b>"stabilized chlorine dioxide in an amount effective to act as the sole preservative in said ophthalmically aqueous acceptable solution" means an amount so that a 99.9% reduction of microbes challenge occur within 14</b></p>

Asserted Claim of '078 patent	Allergan's Proposed Construction <sup>2</sup>	Apotex's Proposed Construction
	<p>reduction of microbes challenge occur within 14 days of contact with the product being tested; and that no growth of yeast and fungi occur.” is necessary or appropriate.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See e.g.</i>, col. 2, lines 35-36; 61-66; col. 3, lines 13-21; and 4:15-23; Examples I-VIII</p> <p>See citations for Claim 1 above.</p>	<p><b>days of contact with the product being tested; and that no growth of yeast and fungi occur.</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>See, e.g., '078 patent, column 8, lines 40-43.</p>
at least one ophthalmically acceptable buffer component in an amount effective to maintain said ophthalmically acceptable aqueous solution at a pH in the range of about 6.8 to about 8,	Agreed-upon construction: The claimed solution requires the inclusion of at least one ophthalmically acceptable buffer component in an amount effective to maintain the ophthalmically acceptable aqueous solution at a pH in the range of approximately 6.8 to approximately 8.	
and at least one ophthalmically acceptable tonicity component in an amount effective to maintain said ophthalmically acceptable aqueous solution at an osmolality in the range of about 200 to about 400 mOsmol/kg,	The claimed solution requires the inclusion of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the ophthalmically acceptable aqueous solution at an osmolality in the range of approximately 200	The claimed solution requires the inclusion of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the ophthalmically acceptable aqueous solution at an osmolality in the range of approximately 200

Asserted Claim of '078 patent	Allergan's Proposed Construction <sup>2</sup>	Apotex's Proposed Construction
	<p>mOsmol/kg to approximately 400 mOsmol/kg.</p> <p>Allergan disagrees with Apotex that the language “‘Ophthalmically acceptable tonicity component’ is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.” is necessary or appropriate.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>See, e.g., '078 patent, col. 2, lines 20-58; col. 2, lines 61-68; col. 4, lines 1-23; col. 5, lines 13-44; Examples I-VIII</p> <p>See citations for Claim 1 above.</p>	<p>mOsmol/kg to approximately 400 mOsmol/kg.</p> <p><b>“Ophthalmically acceptable tonicity component” is defined in the specification as any tonicity component or components “provided that such component or components are compatible with the other ingredients of the ophthalmic formulation and do not have deleterious or toxic properties which could harm the eye.”</b></p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p>The limitation of “an amount effective to maintain the formulation at an osmolality in the range of about 200 to about 400 mOsmol/kg” is supported by the written description at column 5, lines 13-23.</p> <p>The definition of “ophthalmically acceptable tonicity component” is at column 5, lines 24-33.</p>
provided that said preserved	Agreed-upon construction:	

Asserted Claim of '078 patent	Allergan's Proposed Construction <sup>2</sup>	Apotex's Proposed Construction
ophthalmic solution is ophthalmically acceptable and is free of germicidally effective amounts of any positively charged, nitrogen-containing polymers.	The claimed solution is ophthalmically acceptable and free of germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers.	

**'873 patent<sup>3</sup>**

<b>Asserted Claim of '873 Patent</b>	<b>Allergan's Proposed Construction<sup>4</sup></b>	<b>Apotex's Proposed Construction</b>
<b>Claim 1.</b>		
<p>1. A composition comprising:</p> <p>a therapeutically active component selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof, and being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered;</p>	<p>The claimed composition contains a component selected from the group consisting of an alpha-2-adrenergic agonist and mixtures thereof, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient to whom the composition is administered.</p> <p>Allergan disagrees with Apotex that the language "with respect to brimonidine tartrate, at the time of filing, included the range of .2% to .5%" is necessary or proper for claim construction.</p>	<p>The claimed composition contains a component selected from the group consisting of an alpha-2-adrenergic agonist and mixtures thereof, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient to whom the composition is administered.</p> <p><b>"being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered" with respect to brimonidine tartrate, at the time of filing, included the range of .2% to .5%.</b></p> <p>See '873 patent, Table I (0.5%); Table III (0.2%).</p>
<p>a solubility enhancing component, other than a cyclodextrin, in an amount effective to increase the solubility of the therapeutically active</p>	<p>The claimed composition contains a solubility enhancing component, which is a component other than a cyclodextrin that enhances the solubility of the</p>	<p>The claimed composition contains an amount of a solubility enhancing component, which is a component other than a cyclodextrin that solubilizes</p>

<sup>3</sup> Allergan and Apotex agree on the construction for many of the claim terms. There are, however, a few where Allergan and Apotex agree as to a portion of the construction but the remainder is in dispute. To facilitate the Court's review of this joint claim chart, where a portion of the construction of the term is in dispute but not the entire construction, the disputed portion is in bold.

<sup>4</sup> Because the claim language itself is clear and unambiguous, no resort to the specification and prosecution history is necessary, therefore, the best evidence that the plain and ordinary meaning of the claim terms controls is the claims themselves. For brevity, citation to the claim language itself will not be repeated each time as the claim language is provided in Column 1.

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
component in the composition relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component;	<p>therapeutically active component relative to its solubility in a similar composition without the solubility enhancing component.</p> <p><i>See e.g., '873 patent, col. 1, lines 13-18; col. 1, lines 43-53; col. 2, lines 3-6; col. 3, lines 1-9; col. 4, lines 38-52; col. 5, lines 3-10.</i></p>	<p>more of the therapeutically active component relative to a similar composition without the solubility enhancing component.</p> <p><i>See '873 patent, Column 16, lines 20-62, Table IV, Fig. 1.</i></p>
an oxy-chloro component in an effective amount to at least aid in preserving the composition;	Agreed-upon construction: The claimed composition contains an oxy-chloro component in an effective amount to at least aid in preserving the composition	
and a liquid carrier component.	Agreed-upon construction: The claimed composition contains a liquid carrier component.	
<b>Claim 2.</b>		
2. The composition of claim 1 wherein the therapeutically active component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, and mixtures thereof.	Agreed-upon construction: Claim 2 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, and mixtures thereof.	
<b>Claim 3.</b>		
3. The composition of claim 1 wherein the therapeutically active component includes a quinoxaline component.	Agreed-upon construction: Claim 3 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component includes a quinoxaline component.	
<b>Claim 4.</b>		
4. The composition of claim 3 wherein the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof.	Agreed-upon construction: Claim 4 includes all of the limitations of claim 3, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof.	
<b>Claim 5.</b>		
5. The composition of claim 3	Claim 5 includes all of the	Claim 5 includes all of the

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
<p>wherein the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and mixtures thereof.</p>	<p>limitations of claim 3, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, brimonidine, and brimonidine tartrate, and mixtures thereof.</p> <p>Allergan disagrees with Apotex that the language ““being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered” as recited in claim 1, with respect to a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, as recited in claim 5, at the time of filing, included the range of .2% to .5%.” is necessary or proper for claim construction.</p>	<p>limitations of claim 3, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, brimonidine, and brimonidine tartrate, and mixtures thereof.</p> <p><b>"being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered" as recited in claim 1, with respect to a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, as recited in claim 5, at the time of filing, included the range of .2% to .5%.</b></p> <p>See '873 patent, Table I (0.5%); Table III (0.2%).</p>
<b>Claim 6.</b>		
<p>6. The composition of claim 1 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.</p>	<p>Claim 6 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component comprises brimonidine tartrate.</p> <p>Allergan disagrees with Apotex that the language ““being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered” as recited in claim 1, with respect to a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline</p>	<p>Claim 6 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component comprises brimonidine tartrate.</p> <p><b>"being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered" as recited in claim 1, with respect to a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, as recited in</b></p>

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
	<p>quinoxaline, as recited in claim 6, at the time of filing, included the range of .2% to .5%." is necessary or proper for claim construction.</p>	<p><b>claim 6, at the time of filing, included the range of .2% to .5%.</b></p> <p><i>See '873 patent, Table I (0.5%); Table III (0.2%).</i></p>
<b>Claim 7.</b>	<p>7. The composition of claim 1 wherein the therapeutically active component has increased diffusion through a lipid membrane relative to an identical therapeutically active component in a similar composition without the solubility enhancing component.</p> <p>Claim 7 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component has increased diffusion through a lipid membrane relative to an identical therapeutically active component in a similar composition without the solubility enhancing component.</p> <p>Allergan does not agree with Apotex that the language "increased diffusion through a lipid membrane" means increased movement through a biological membrane composed of lipid molecules, including cell membranes, is necessary or appropriate as the claim is clear on its face.</p> <p><i>See e.g. Claim 7; col. 5, lines 3-31; col. 8, lines 11-18.</i></p>	<p>Claim 7 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component has increased diffusion through a lipid membrane relative to an identical therapeutically active component in a similar composition without the solubility enhancing component.</p> <p><b>"increased diffusion through a lipid membrane" means increased movement through a biological membrane composed of lipid molecules, including cell membranes.</b></p> <p>'873 patent, column 5, lines 3-17, column 8, lines 11-18.</p>
<b>Claim 8.</b>	<p>8. The composition of claim 1 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the therapeutically active component relative to the solubility in a biological environment of an identical</p> <p>Claim 8 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is effective to <b>increase the solubility in a biological environment of the therapeutically active component</b> relative to the solubility in a biological</p>	<p>Claim 8 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is effective to <b>solubilize more in a biological environment of the therapeutically active component</b> relative to the solubility in a biological environment of an identical therapeutically active</p>

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
therapeutically active component in a similar composition without the solubility enhancing component.	<p>environment of an identical therapeutically active component in a similar composition without the solubility enhancing component.</p> <p>Allergan does not believe that the additional language sought by Apotex; "a "biological environment" means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye," is necessary as the claim is unambiguous on its face.</p> <p>'873 patent, column 5, lines 3-17, column 8, lines 11-18; Claim 8.</p>	<p>component in a similar composition without the solubility enhancing component.</p> <p><b>a "biological environment" means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye.</b></p> <p>'873 patent, column 5, lines 3-17, column 8, lines 11-18.</p>
<b>Claim 9.</b>		
9. The composition of claim 1 wherein the solubility enhancing component comprises a polyanionic component.	Agreed-upon construction: Claim 9 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component comprises a polyanionic component.	
<b>Claim 10.</b>		
10. The composition of claim 9 wherein said polyanionic components is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic acid, anionic polymers derived from amino acids and mixtures thereof.	Agreed-upon construction: Claim 10 includes all of the limitations of claim 9, with the further requirement that the said polyanionic component is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic acid, anionic polymers derived from amino acids and mixtures thereof.	
<b>Claim 11.</b>		
11. The composition of claim	Agreed-upon construction:	

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
1 wherein the solubility enhancing component comprises an anionic cellulose derivative.	Claim 11 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component comprises an anionic cellulose derivative.	
<b>Claim 12.</b>		
12. The composition of claim 1 wherein the solubility enhancing component comprises a carboxymethylcellulose.	<p>Agreed-upon construction:</p> <p>Claim 12 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component comprises a carboxymethylcellulose.</p>	
<b>Claim 13.</b>		
13. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.1% (w/v) to about 30% (w/v).	<p>Agreed-upon construction:</p> <p>Claim 13 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is present in an amount in a range of approximately 0.1% (w/v) to approximately 30% (w/v).</p>	
<b>Claim 14.</b>		
14. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 10 (w/v).	<p>Agreed-upon construction:</p> <p>Claim 14 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is present in an amount in a range of approximately 0.2% (w/v) to approximately 10 (w/v).</p>	
<b>Claim 15.</b>		
15. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v).	<p>Agreed-upon construction:</p> <p>Claim 15 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is present in an amount in a range of approximately 0.2% (w/v) to approximately 0.6% (w/v).</p>	
<b>Claim 16.</b>		
16. The composition of claim 1 wherein the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof.	<p>Agreed-upon construction:</p> <p>Claim 16 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof.</p>	
<b>Claim 17.</b>		
17. The composition of claim 1 wherein the oxy-chloro component comprises a	<p>Agreed-upon construction:</p> <p>Claim 17 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component comprises a</p>	

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
chlorite component.	chlorite component.	
<b>Claim 18.</b>		
18. The composition of claim 1 wherein the oxy-chloro component comprises stabilized chlorine dioxide.	Agreed-upon construction: Claim 18 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component comprises stabilized chlorine dioxide.	
<b>Claim 19.</b>		
19. The composition of claim 1, wherein the oxy-chloro component is present in an amount of about 500 ppm (w/v) or less.	Agreed-upon construction: Claim 19 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component is present in an amount of approximately 500 ppm (w/v) or less.	
<b>Claim 20.</b>		
20. The composition of claim 1 wherein the oxy-chloro component is present in an amount in a range of about 10 ppm (w/v) to about 200 ppm (w/v).	Agreed-upon construction: Claim 20 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component is present in an amount in a range of approximately 10 ppm (w/v) to approximately 200 ppm (w/v).	
<b>Claim 23.</b>		
23. The composition of claim 1 wherein the liquid carrier is an aqueous liquid carrier component.	Agreed-upon construction: Claim 23 includes all of the limitations of claim 1, with the further requirement that the liquid carrier is an aqueous liquid carrier component.	
<b>Claim 24.</b>		
24. The composition of claim 1 which is a solution.	Agreed-upon construction: Claim 24 includes all of the limitations of claim 1, with the further requirement that the composition of claim 1 is a solution.	
<b>Claim 25.</b>		
25. The composition of claim 1 which has a pH of about 7 or greater.	Agreed-upon construction: Claim 25 includes all of the limitations of claim 1, with the further requirement that has a pH of approximately 7 or greater.	
<b>Claim 26.</b>		
26. The composition of claim 1 which has a pH in a range of about 7 to about 9.	Agreed-upon construction: Claim 26 includes all of the limitations of claim 1, with the further requirement that the composition has a pH in a range of approximately 7 to approximately 9.	
<b>Claim 27.</b>		
27. The composition of claim 1 which is ophthalmically acceptable.	Agreed-upon construction: Claim 27 includes all of the limitations of claim 1, with the further requirement that the composition is ophthalmically acceptable.	

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
<b>Claim 28.</b>		
28. A composition comprising:		
a therapeutically active component selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;	Agreed-upon construction: The claimed composition contains a therapeutically active component selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered.	
an anionic cellulose derivative in an amount effective to increase the solubility of the therapeutically active component;	The claimed composition contains an anionic cellulose derivative <b>in an amount effective to increase the solubility of the therapeutically active component.</b>	The claimed composition contains an anionic cellulose derivative <b>in an amount effective to solubilize more of the therapeutically active component.</b>
	<i>See e.g., '873 patent, col. 1, lines 13-18; col. 1, lines 43-53; col. 2, lines 3-6; col. 3, lines 1-9; col. 4, lines 38-52; col. 5, lines 3-10; Examples I and II including the figure and tables.</i>	
a chlorite component in an effective amount to at least aid in preserving the composition;	Agreed-upon construction: The claimed composition contains a chlorite component in an effective amount to at least aid in preserving the composition	
and an aqueous liquid carrier component.	Agreed-upon construction: The claimed composition contains an aqueous liquid carrier component.	
<b>Claim 29.</b>		
29. The composition of claim 28 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.	Claim 29 includes all of the limitations of claim 28, with the further requirement that the therapeutically active component comprises brimonidine tartrate.	Claim 29 includes all of the limitations of claim 28, with the further requirement that the therapeutically active component comprises brimonidine tartrate.
	Allergan disagrees with Apotex that the language	<b>"being present in an amount effective to provide a</b>

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
	<p>"being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered" as recited in claim 28, with respect to a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, as recited in claim 29, at the time of filing, included the range of .2% to .5%." is necessary or proper for claim construction.</p>	<p><b>desired therapeutic benefit to a patient to whom the composition is administered" as recited in claim 28, with respect to a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, as recited in claim 29, at the time of filing, included the range of .2% to .5%.</b></p> <p><i>See '873 patent, Table I (0.5%); Table III (0.2%).</i></p>
<b>Claim 30.</b>		
30. The composition of claim 28 wherein the anionic cellulose derivative comprises carboxymethylcellulose.	<p>Agreed-upon construction:</p> <p>Claim 30 includes all of the limitations of claim 28, with the further requirement that the anionic cellulose derivative comprises carboxymethylcellulose.</p>	
<b>Claim 31.</b>		
31. The composition of claim 28 wherein the anionic cellulose derivative is present in an amount in a range of about 0.2% to about 0.6% (w/v).	<p>Agreed-upon construction:</p> <p>Claim 31 includes all of the limitations of claim 28, with the further requirement that the anionic cellulose derivative is present in an amount in a range of approximately 0.2% to approximately 0.6% (w/v).</p>	
<b>Claim 32.</b>		
<p>32. A composition comprising:</p> <p>a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;</p>	<p>The claimed composition contains brimonidine tartrate in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered.</p> <p>Allergan disagrees with Apotex that the language "an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered" of a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino)</p>	<p>The claimed composition contains brimonidine tartrate in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered.</p> <p><b>"an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered" of a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, at</b></p>

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
	quinoxaline, at the time of filing, included the range of ".2% to .5%." is necessary or appropriate for claim construction.	<p><b>the time of filing, included the range of .2% to .5%.</b></p> <p><i>See '873 patent, Table I (0.5%); Table III (0.2%).</i></p>
a solubility enhancing component in an amount effective to increase the solubility of the tartrate of 5-bromo-6-(2-imidazolin-2-ylamino) quinoxaline;	<p>The claimed composition contains a solubility enhancing component <b>in an amount effective to increase the solubility of brimonidine tartrate.</b></p> <p>Allergan disagrees with Apotex that the language "Additional solubility enhancing components, such as cyclodextrins, are not excluded by this claim language," is necessary or appropriate for claim construction.</p>	<p>The claimed composition contains a solubility enhancing component <b>in an amount effective to solubilize more of brimonidine tartrate.</b></p> <p><b>Additional solubility enhancing components, such as cyclodextrins, are not excluded by this claim language.</b></p>
a chlorite component in an effective amount to at least aid in preserving the composition;	Agreed-upon construction: The claimed composition contains a chlorite component in an effective amount to at least aid in preserving the composition.	
and an aqueous liquid carrier component.	Agreed-upon construction: The claimed composition contains an aqueous liquid carrier component.	
<b>Claim 33.</b>		
33. The composition of claim 32 wherein the solubility enhancing component comprises a carboxymethylcellulose.	Agreed-upon construction: Claim 33 includes all of the limitations of claim 32, with the further requirement that the solubility enhancing component comprises a carboxymethylcellulose.	
<b>Claim 34.</b>		
34. The composition of claim 32 which is ophthalmically acceptable.	Agreed-upon construction: Claim 34 includes all of the limitations of claim 32, with the further requirement that the composition of claim 32 is ophthalmically acceptable.	
<b>Claim 35.</b>		
35. A composition comprising:		

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
a therapeutically active component in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered;	Agreed-upon construction: The claimed composition contains a therapeutically active component in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered.	
an oxy-chloro component in an effective amount to at least aid in preserving the composition;	Agreed-upon construction: The claimed composition contains an oxy-chloro component in an effective amount to at least aid in preserving the composition.	
and a liquid carrier component, wherein the composition is substantially free of cyclodextrins.	Agreed-upon construction: The claimed composition contains a liquid carrier component, wherein the composition is substantially free of cyclodextrins.	
<b>Claim 36.</b>		
36. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of antibacterials, antihistamines, decongestants, antiinflammatories, antiparasitics, miotics, anticholinergics, adrenergics, antivirals, local anesthetics, antifungals, amoebicidals, trichomonocidals, analgesics, mydriatics, antiglaucoma drugs, carbonic anhydrase inhibitors, ophthalmic diagnostic agents, ophthalmic agents used as adjuvants in surgery, chelating agents, antineoplastics, antihypertensives, muscle relaxants, diagnostics, and mixtures thereof.	Agreed-upon construction: Claim 36 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of antibacterials, antihistamines, decongestants, antiinflammatories, antiparasitics, miotics, anticholinergics, adrenergics, antivirals, local anesthetics, antifungals, amoebicidals, trichomonocidals, analgesics, mydriatics, antiglaucoma drugs, carbonic anhydrase inhibitors, ophthalmic diagnostic agents, ophthalmic agents used as adjuvants in surgery, chelating agents, antineoplastics, antihypertensives, muscle relaxants, diagnostics, and mixtures thereof.	
<b>Claim 37.</b>		
37. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of	Agreed-upon construction: Claim 37 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of adrenergic agonists	

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction	
adrenergic agonists and mixtures thereof.	and mixtures thereof.		
<b>Claim 38.</b> 38. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof.		Agreed-upon construction: Claim 38 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof.	
<b>Claim 39.</b> 39. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, and mixtures thereof.		Agreed-upon construction: Claim 39 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, and mixtures thereof.	
<b>Claim 40.</b> 40. The composition of claim 35 wherein the therapeutically active component includes a quinoxaline component.		Agreed-upon construction: Claim 40 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component includes a quinoxaline component.	
<b>Claim 41.</b> 41. The composition of claim 40 wherein the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof.		Agreed-upon construction: Claim 41 includes all of the limitations of claim 40, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof.	
<b>Claim 42.</b> 42. The composition of claim 40 wherein the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and tartrate of 5-bromo-6-(2-imidozolin-2-ylamino)		Claim 42 includes all of the limitations of claim 40, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, brimonidine, and brimonidine tartrate, and mixtures thereof.	Claim 42 includes all of the limitations of claim 40, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, brimonidine, and brimonidine tartrate, and mixtures thereof.

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
quinoxaline, and mixtures thereof.	Allergan disagrees with Apotex that the language ““an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered’ of a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, at the time of filing, included the range of .2% to .5%” is necessary or appropriate for claim construction.	<p><b>“an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered” of a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, at the time of filing, included the range of .2% to .5%.</b></p> <p>See '873 patent, Table I (0.5%); Table III (0.2%).</p>
<b>Claim 43.</b>		
43. The composition of claim 35 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.	Agreed-upon construction: Claim 43 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component comprises brimonidine tartrate.	
<b>Claim 44.</b>		
44. The composition of claim 35, which further includes a solubility enhancing component, other than a cyclodextrin, in an amount effective to increase the solubility of the therapeutically active component in the composition relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component.	Claim 44 includes all of the limitations of claim 35, with the further requirement that the composition of claim 35, further includes a solubility enhancing component, other than a cyclodextrin, <b>in an amount effective to increase the solubility of the therapeutically active component in the composition</b> relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component.	Claim 44 includes all of the limitations of claim 35, with the further requirement that the composition of claim 35, further includes a solubility enhancing component, other than a cyclodextrin, <b>in an amount effective to solubilize more of the therapeutically active component in the composition</b> relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component.
		See e.g., '873 patent, col. 1, lines 13-18; col. 1, lines 43-
		See '873 patent, Column 16, lines 20-62, Table IV, Fig. 1.

Asserted Claim of '873 Patent	Allergan's Proposed Construction <sup>4</sup>	Apotex's Proposed Construction
	53; col. 2, lines 3-6; col. 3, lines 1-9; col. 4, lines 38-52; col. 5, lines 3-10; Examples I and II including the figure and tables. .	
<b>Claim 45.</b>		
45. The composition of claim 44 wherein the solubility enhancing component comprises a polyanionic component.	Agreed-upon construction: Claim 45 includes all of the limitations of claim 44, with the further requirement that the solubility enhancing component comprises a polyanionic component.	
<b>Claim 46.</b>		
46. The composition of claim 35 wherein the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof.	Agreed-upon construction: Claim 46 includes all of the limitations of claim 35, with the further requirement that the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof.	
<b>Claim 47.</b>		
47. The composition of claim 35 wherein the oxy-chloro component comprises a chlorite component.	Agreed-upon construction: Claim 47 includes all of the limitations of claim 35, with the further requirement that the oxy-chloro component comprises a chlorite component.	
<b>Claim 48.</b>		
48. The composition of claim 35 wherein the oxy-chloro component comprises stabilized chlorine dioxide.	Agreed-upon construction: Claim 48 includes all of the limitations of claim 35, with the further requirement that the oxy-chloro component comprises stabilized chlorine dioxide.	
<b>Claim 49.</b>		
49. The composition of claim 35 which is ophthalmically acceptable.	Agreed-upon construction: Claim 49 includes all of the limitations of claim 35, with the further requirement that the composition of claim 35 is ophthalmically acceptable.	

**'210 patent**

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
<b>Claim 1</b>		
1. A therapeutically effective aqueous composition comprising:	Agreed-upon construction: The claim requires a therapeutically effective aqueous composition.	
a therapeutically active alpha-2-adrenergic agonist component selected from the group consisting of 5-bromo-6-(2-imidazolin-2-ylamino) quinoxaline, a salt thereof, and an ester thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;	The claimed composition comprises a therapeutically active alpha-2-adrenergic agonist component, and that component is selected from the group consisting of brimonidine, salts of brimonidine, or esters of brimonidine, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient.	The claimed composition comprises a therapeutically active alpha-2-adrenergic agonist component, and that component is selected from the group consisting of brimonidine, salts of brimonidine, or esters of brimonidine, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient.
	Allergan disagrees with Apotex that the phrase "At the time of filing of the '210 patent, this amount included the range of 0.2% to 0.5% brimonidine tartrate," is necessary or appropriate for claim construction.	<b>At the time of filing of the '210 patent, this amount included the range of 0.2% to 0.5% brimonidine tartrate.</b>  <i>See, e.g.</i> , '210 patent col. 2, lines 22-26; '210 patent file history, Reply to office action, dated Mar. 11, 2003.
and a polyanionic solubility enhancing component in an	<i>See, e.g.</i> , '210 patent col. 2, lines 22-26; '210 patent file history, Reply to office action, dated Mar. 11, 2003.	See '210 patent, Table I (0.5%); Table III (0.2%).
	The claimed composition comprises a polyanionic	The claimed composition comprises a polyanionic

<sup>5</sup> Because the claim language itself is clear and unambiguous, no resort to the specification and prosecution history is necessary, therefore, the best evidence that the plain and ordinary meaning of the claim terms controls is the claims themselves. For brevity, citation to the claim language itself will not be repeated each time as the claim language is provided in Column 1.

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.	<p>solubility enhancing component, which is a component that enhances the solubility of the alpha-2-adrenergic agonist component. <b>The solubility enhancing component is present in such an amount that the solubility of the alpha-2-adrenergic agonist component in the composition is increased relative to its solubility in a similar composition without the solubility enhancing component.</b></p>	<p>solubility enhancing component, which is a component that enhances the solubility of the alpha-2-adrenergic agonist component. <b>The solubility enhancing component is present in such an amount that more of the alpha-2-adrenergic agonist component is solubilized in the composition relative to a similar composition without the solubility enhancing component.</b></p>
	<p><i>See, e.g.,</i> '210 patent abstract; col. 2, lines 5-21 and 49-56; col. 4, lines 52-57; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</p>	<p><i>See, e.g.,</i> '210 patent, Column 15, line 28 – column 16, lines 23, Table IV, Fig. 1.</p>
<b>Claim 2</b>		
2. The composition of claim 1 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.	Agreed-upon construction: Claim 2 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component comprises brimonidine tartrate.	
<b>Claim 3</b>		
3. The composition of claim 1 wherein the therapeutically active component is substantially unionized.	Agreed-upon construction: Claim 3 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component is substantially unionized.	
<b>Claim 4</b>		
4. The composition of claim 1 wherein the therapeutically active component is substantially unionized in a	Claim 4 includes all the limitations of claim 1, with the additional requirement that the therapeutically active	Claim 4 includes all the limitations of claim 1, with the additional requirement that the therapeutically active

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
<p>biological environment to which the composition is administered.</p>	<p>component is substantially unionized in a biological environment to which the composition is administered.</p> <p>Allergan disagrees with Apotex that "a "biological environment" means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye." Is necessary for claim construction as the claim is clear on its face.</p> <p><i>See, e.g. claim 4 and col. 1, line 53 - col. 2, line 4; col. 4, lines 33-51</i></p>	<p>component is substantially unionized in a biological environment to which the composition is administered.</p> <p><b>a "biological environment" means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye.</b></p> <p>See, e.g., '210 patent, column 1, lines 59-60, column 4, lines 33-51.</p>
<b>Claim 5</b>		
<p>5. The composition of claim 1 wherein the therapeutically active component has increased diffusion through a lipid membrane relative to an identical therapeutically active component in a similar composition the solubility enhancing component.</p>	<p>Claim 5 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component has increased diffusion through a lipid membrane relative to its diffusion in a similar composition.</p> <p>Allergan disagrees with Apotex that the language "increased diffusion through a lipid membrane" means increased movement through a biological membrane composed of lipid molecules, including cell membranes," is necessary or appropriate.</p> <p><i>See, e.g., '210 patent col. 4, lines 44-48; col. 5, lines 66- col. 6 line 7.</i></p>	<p>Claim 5 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component has increased diffusion through a lipid membrane relative to its diffusion in a similar composition.</p> <p><b>"increased diffusion through a lipid membrane" means increased movement through a biological membrane composed of lipid molecules, including cell membranes.</b></p> <p><i>See, e.g., '210 patent col. 4, lines 44-48.</i></p> <p><i>See, e.g., '210 patent, column 5, line 66 - column 6, line 7.</i></p>

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
<b>Claim 6</b>		
<p>6. The composition of claim 1 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the therapeutically active component relative to the solubility in a biological environment of an identical therapeutically active component in a similar composition without the solubility enhancing component.</p>	<p>Claim 6 includes all the limitations of claim 1, with the additional requirement that <b>the solubility enhancing component is effective to increase the solubility of the therapeutically active component in a biological environment relative to its solubility in a biological environment without the solubility enhancing component.</b></p> <p>Allergan disagrees with Apotex that "a 'biological environment' means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye," is necessary for claim construction as the claim is clear on its face.</p> <p><i>See, e.g., claim 5 and col. 1, line 53-col. 2, line 4; col. 4, lines 33-51.</i></p> <p><i>See, e.g., '210 patent abstract; col. 4, lines 33-51.</i></p>	<p>Claim 6 includes all the limitations of claim 1, with the additional requirement that <b>the solubility enhancing component is effective to solubilize more of the therapeutically active component in a biological environment relative to its solubility in a biological environment without the solubility enhancing component.</b></p> <p><b>a "biological environment" means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye.</b></p> <p><i>See, e.g., '210 patent abstract; col. 4, lines 33-51.</i></p> <p><i>See, e.g., '210 patent, column 1, lines 59-60, column 4, lines 33-51.</i></p>
<b>Claim 7</b>		
<p>7. The composition of claim 1 wherein said polyanionic component is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic</p>	<p>Agreed-upon construction:</p> <p>Claim 7 includes all the limitations of claim 1, with the additional requirement that the polyanionic component is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic acid, or anionic polymers derived from amino acids and mixtures thereof.</p>	

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
polymers derived from alginic acid, anionic polymers derived from amino acids and mixtures thereof.		
<b>Claim 8</b>		
8. The composition of claim 1 wherein the solubility enhancing component is selected from the group consisting of anionic cellulose derivatives and mixtures thereof.	Agreed-upon construction: Claim 8 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is selected from the group consisting of anionic cellulose derivatives or a mixtures thereof.	
<b>Claim 9</b>		
9. The composition of claim 1 wherein the solubility enhancing component is selected from the group consisting of carboxymethylcelluloses and derivatives thereof.	Agreed-upon construction: Claim 9 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is selected from the group consisting of carboxymethylcelluloses and derivatives thereof.	
<b>Claim 10</b>		
10. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.1% (w/v) to about 30% (w/v).	Agreed-upon construction: Claim 10 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is present in the composition in an amount of approximately 0.1% (w/v) to approximately 30% (w/v).	
<b>Claim 11</b>		
11. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 10% (w/v).	Agreed-upon construction: Claim 11 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is present in the composition in an amount of approximately 0.2% (w/v) to approximately 10% (w/v).	
<b>Claim 12</b>		
12. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v).	Agreed-upon construction: Claim 12 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is present in the composition in an amount of approximately 0.2% (w/v) to approximately 0.6% (w/v).	
<b>Claim 13</b>		
13. The composition of claim 1 which has a pH of about 7	Agreed-upon construction: Claim 13 includes all the limitations of claim 1, with the	

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
or greater.	additional requirement that the pH of the composition is approximately 7 or greater.	
<b>Claim 14</b>		
14. The composition of claim 1 which has a pH in a range of about 7 to about 9.	Agreed-upon construction: Claim 14 includes all the limitations of claim 1, with the additional requirement that the pH of the composition is in the range of approximately 7 to approximately 9.	
<b>Claim 15</b>		
15. The composition of claim 1 which is ophthalmically acceptable.	Agreed-upon construction: Claim 15 includes all the limitations of claim 1, with the additional requirement that the composition is ophthalmically acceptable.	
<b>Claim 16</b>		
16. A therapeutically effective aqueous composition comprising:	Agreed-upon construction: The claim requires a therapeutically effective aqueous composition.	
a therapeutically active component selected from the group consisting of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, a salt thereof, and an ester thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;	The claimed composition comprises a therapeutically active component, and that component is selected from the group consisting of brimonidine, salts of brimonidine, or esters of brimonidine, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient.	The claimed composition comprises a therapeutically active component, and that component is selected from the group consisting of brimonidine, salts of brimonidine, or esters of brimonidine, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient.
	Allergan does not agree with Apotex that the language "At the time of filing of the application, 0.2% to 0.5% was an amount of brimonidine tartrate known to be effective to provide a therapeutic benefit to a patient to whom the composition is administered," is necessary or appropriate for claim construction.  <i>See, e.g., '210 patent col. 2, lines 22-26; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</i>	<b>At the time of filing of the application, 0.2% to 0.5% was an amount of brimonidine tartrate known to be effective to provide a therapeutic benefit to a patient to whom the composition is administered.</b>  <i>See, e.g., '210 patent, Table I</i>

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
	history, Reply to office action, dated Mar. 11, 2003.	(0.5%), Table III (02%).
and an anionic cellulose derivative in an amount effective to increase the solubility of the therapeutically active component.	<p>The claimed composition comprises <b>an anionic cellulose derivative, and that anionic cellulose derivative is present in an amount effective to increase the solubility of the therapeutically active component.</b></p> <p><i>See, e.g.,</i> '210 patent abstract; '210 patent col. 8, lines 15-20; col. 2, lines 5-21 and 49-56; col. 3:4-13 and 22-24; col. 4:1-27, and 52-57; 6:8-38; 14:53-16:26; Examples I and II including the figure and tables; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</p>	<p>The claimed composition comprises <b>an anionic cellulose derivative, and that anionic cellulose derivative is present in an amount effective to solubilize more of the therapeutically active component.</b></p> <p><i>See, e.g.,</i> '210 patent col. 8, lines 15-20; col. 2, lines 5-21; col. 3, lines 22-24; col. 4, lines 52-57; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</p>
<b>Claim 17</b>		
17. The composition of claim 16 wherein the alpha-2-adrenergic agonist component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.	Agreed-upon construction: Claim 17 includes all the limitations of claim 16, with the additional requirement that the alpha-2-adrenergic agonist component comprises brimonidine tartrate.	
<b>Claim 18</b>		
18. The composition of claim 16 wherein the anionic cellulose derivative comprises carboxymethylcellulose.	Agreed-upon construction: Claim 18 includes all the limitations of claim 16, with the additional requirement that the anionic cellulose derivative comprises carboxymethylcellulose.	
<b>Claim 19</b>		
19. The composition of claim 16 wherein the anionic cellulose derivative is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v).	Agreed-upon construction: Claim 19 includes all the limitations of claim 16, with the additional requirement that the anionic cellulose derivative is present in an amount in a range of approximately 0.2% (w/v) to approximately 0.6% (w/v).	
<b>Claim 20</b>		

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
20. A therapeutically effective aqueous composition comprising:	Agreed-upon construction: The claim requires a therapeutically effective aqueous composition.	
a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;	<p>The claimed composition comprises brimonidine tartrate in an amount effective to provide a therapeutic benefit to a patient.</p> <p>Allergan disagrees with Apotex that the language “At the time of filing of the application, 0.2% to 0.5% was an amount of brimonidine tartrate known to be effective to provide a therapeutic benefit to a patient to whom the composition is administered,” is necessary or appropriate for claim construction.</p> <p><i>See, e.g., '210 patent col. 2, lines 30-39; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</i></p> <p><i>See, e.g., '210 patent col. 2, lines 30-39; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</i></p>	<p>The claimed composition comprises brimonidine tartrate in an amount effective to provide a therapeutic benefit to a patient.</p> <p><b>At the time of filing of the application, 0.2% to 0.5% was an amount of brimonidine tartrate known to be effective to provide a therapeutic benefit to a patient to whom the composition is administered.</b></p> <p><i>See, e.g., '210 patent col. 2, lines 30-39; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</i></p> <p><i>See, e.g., '210 patent, Table I (0.5%), Table III (02%).</i></p>
and an anionic solubility enhancing component in an amount effective to increase the solubility of the tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline	<p><b>The claimed composition comprises an anionic solubility enhancing component in an amount effective to increase the solubility of brimonidine tartrate.</b></p> <p><i>See, e.g., '210 patent abstract; '210 patent col. 8, lines 15-20; col. 2, lines 5-21 and 49-56; col. 3:4-13 and 22-24; col. 4:1-27, and 52-57; 6:8-38; 14:53-16:26; Examples I and II including the figure and tables; '210 patent file history, Reply to office action, dated</i></p>	<p><b>The claimed composition comprises an anionic solubility enhancing component in an amount effective to solubilize more of brimonidine tartrate.</b></p> <p><i>See, e.g., '210 patent col. 2, lines 5-21 and 49-56; col. 4, lines 52-57; '210 patent file history, Reply to office action, dated Mar. 11, 2003.</i></p>

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
	Mar. 11, 2003.	
<b>Claim 21</b>		
21. The composition of claim 20 wherein the solubility enhancing component comprises a carboxymethylcellulose.	Agreed-upon construction: Claim 21 includes all the limitations of claim 20, with the additional requirement that solubility enhancing component comprises a carboxymethylcellulose.	
<b>Claim 22</b>		
22. The composition of claim 20 which is ophthalmically acceptable.	Agreed-upon construction: Claim 22 includes all the limitations of claim 20, with the additional requirement that the composition is ophthalmically acceptable.	
<b>Claim 23</b>		
23. The composition of claim 1 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition.	Agreed-upon construction: Claim 23 includes all the limitations of claim 1, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition.	
<b>Claim 25</b>		
25. The composition of claim 23 in which the preservative comprises an oxy-chloro component.	Agreed-upon construction: Claim 25 includes all the limitations of claim 23, with the additional requirement that the preservative comprises an oxy-chloro component.	
<b>Claim 26</b>		
26. The composition of claim 23 in which the preservative comprises a chlorite component.	Agreed-upon construction: Claim 26 includes all the limitations of claim 23, with the additional requirement that the preservative comprises a chlorite component.	
<b>Claim 27</b>		
27. The composition of claim 16 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition.	Agreed-upon construction: Claim 27 includes all the limitations of claim 16, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition.	
<b>Claim 29</b>		
29. The composition of claim	Agreed-upon construction:	

Asserted Claim of '210 Patent	Allergan's Proposed Construction <sup>5</sup>	Apotex's Proposed Construction
27 in which the preservative comprises an oxy-chloro component.	Claim 29 includes all the limitations of claim 27, with the additional requirement that the preservative comprises an oxy-chloro component.	
<b>Claim 30</b>		
30. The composition of claim 27 in which the preservative comprises a chlorite component.	Agreed-upon construction: Claim 30 includes all the limitations of claim 27, with the additional requirement that the preservative comprises a chlorite component.	
<b>Claim 31</b>		
31. The composition of claim 20 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition.	Agreed-upon construction: Claim 31 includes all the limitations of claim 20, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition.	
<b>Claim 33</b>		
33. The composition of claim 31 in which the preservative comprises an oxy-chloro component.	Agreed-upon construction: Claim 33 includes all the limitations of claim 31, with the additional requirement that the preservative comprises an oxy-chloro component.	
<b>Claim 34</b>		
34. The composition of claim 31 in which the preservative comprises a chlorite component.	Agreed-upon construction: Claim 33 includes all the limitations of claim 31, with the additional requirement that the preservative comprises a chlorite component.	

**'337 patent**

Asserted Claim of '337 Patent	Allergan's Proposed Construction <sup>6</sup>	Apotex's Proposed Construction
<b>Claim 1</b>		
<p>1. A therapeutically effective ophthalmic composition comprising:</p> <p>an alpha-2-adrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient in whom the composition is administered; and</p> <p>a solubility enhancing component other than a cyclodextrin in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.</p>	<p>Agreed-upon construction:</p> <p>The claim requires a therapeutically effective ophthalmic composition.</p> <p>Agreed-upon construction:</p> <p>The claimed composition contains an alpha-2-adrenergic agonist component, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient.</p> <p>The claimed composition contains a solubility enhancing component, which is a component that enhances the solubility of the alpha-2-adrenergic agonist component, and any solubility enhancing component other than a cyclodextrin is covered by the claim. <b>The solubility enhancing component is present in such an amount that the solubility of the alpha-2-adrenergic agonist component in the composition is increased relative to its solubility in a similar composition without the solubility enhancing component.</b></p> <p><i>See, e.g., '337 patent, abstract; col. 1:57-2:26; col. 2:13-20; col. 3:8-17; col. 4:60-65; col. 6:17-41; Examples I and II including the figure and tables; '337 patent file history, Reply to office action, dated June 16, 2003.</i></p>	<p>The claimed composition contains a solubility enhancing component, which is a component that enhances the solubility of the alpha-2-adrenergic agonist component, and any solubility enhancing component other than a cyclodextrin is covered by the claim. <b>The solubility enhancing component is present in such an amount that the more of the alpha-2-adrenergic agonist component in the composition is solubilized relative to a similar composition without the solubility enhancing component.</b></p> <p><i>See, e.g., '337 patent, abstract; col. 2, lines 13-20; col. 4, lines 60-65; col. 6, lines 17-41; '337 patent file history, Reply to office action, dated June 16, 2003.</i></p>

<sup>6</sup> Because the claim language itself is clear and unambiguous, no resort to the specification and prosecution history is necessary, therefore, the best evidence that the plain and ordinary meaning of the claim terms controls is the claims themselves. For brevity, citation to the claim language itself will not be repeated each time as the claim language is provided in Column 1.

Asserted Claim of '337 Patent	Allergan's Proposed Construction <sup>6</sup>	Apotex's Proposed Construction
<b>Claim 2</b>		
2. The composition of claim 1 wherein the alpha-2-adrenergic component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, derivatives thereof, and mixtures thereof.	<p>Agreed-upon construction:</p> <p>Claim 2 contains all the limitations of claim 1, with the additional requirement that the alpha-2-adrenergic agonist component is selected from the group consisting of an imino-imidazoline, imidazoline, imidazole, azepine, thiazine, oxazoline, guanidine, catecholamine, derivative thereof, or mixture thereof.</p>	
<b>Claim 3</b>		
3. The composition of claim 1 wherein the therapeutically active component includes a quinoxaline component.	<p>Agreed-upon construction:</p> <p>Claim 3 includes all the limitations of claim 1, with the further requirement that the composition includes a quinoxaline component.</p>	
<b>Claim 4</b>		
4. The composition of claim 3 wherein the quinoxaline component is selected from the group consisting of quinoxaline, derivatives thereof, and mixtures thereof.	<p>Agreed-upon construction:</p> <p>Claim 4 includes all the limitations of claim 3, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, derivatives of quinoxaline, or mixtures of quinoxaline.</p>	
<b>Claim 5</b>		
5. The composition of claim 1 wherein said solubility enhancing component comprises an anionic polymer.	<p>Agreed-upon construction:</p> <p>Claim 5 includes all the limitations of claim 1, with the further requirement that the solubility enhancing component comprises an anionic polymer.</p>	
<b>Claim 6</b>		
6. The composition of claim 1 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological	<p>Claim 6 includes all the limitations of claim 1, with the further requirement that <b>the solubility enhancing component is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to its solubility in a composition without the solubility enhancing</b></p>	<p>Claim 6 includes all the limitations of claim 1, with the further requirement that <b>the solubility enhancing component is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological</b></p>

Asserted Claim of '337 Patent	Allergan's Proposed Construction <sup>6</sup>	Apotex's Proposed Construction
<p>environment of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.</p> <p><i>See, e.g.</i>, '337 patent, abstract; col. 1:57-2:26; col. 2:13-20; col. 3:8-17; col. 4:41-59 and 60-65; col. 6:17-41; '337 patent file history, Reply to office action, dated June 16, 2003.</p> <p>Allergan disagrees with Apotex that the language "a 'biological environment' means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye," is necessary as the claim is clear on its face.</p>	<p><b>component.</b></p>	<p><b>environment of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.</b></p> <p><b>A "biological environment" means an portion of the patient's body being treated by the therapeutically active component, including the cornea of an eye.</b></p>
<b>Claim 7</b>		
<p>7. The composition of claim 6 wherein the solubility enhancing component comprises an anionic polymer.</p>	<p>Agreed-upon construction: Claim 7 includes all the limitations of claim 6, with the further requirement that the solubility enhancing component comprises an anionic polymer.</p>	
<b>Claim 8</b>		
<p>8. The composition of claim 3 wherein said solubility enhancing component comprises an anionic polymer.</p>	<p>Agreed-upon construction: Claim 8 includes all the limitations of claim 3, with the further requirement that the solubility enhancing component comprises an anionic polymer.</p>	
<b>Claim 9</b>		
<p>9. The composition of claim 1 which further comprises an effective amount of a preservative.</p> <p><i>See e.g.</i>, col. 3, lines 49-61; col. 9, lines 43-45.</p>	<p>Claim 9 includes all the limitations of claim 1 with the further requirement that the composition further comprises a <b>component that assists in the preservation of the composition.</b></p>	<p>Claim 9 includes all the limitations of claim 1 with the further requirement that the composition <b>further comprises an effective amount of a preservative.</b></p>

Asserted Claim of '337 Patent	Allergan's Proposed Construction <sup>6</sup>	Apotex's Proposed Construction
<b>Claim 10</b>		
10. The composition of claim 6 which further comprises an effective amount of a preservative.	<p>Claim 10 includes all the limitations of claim 6 with the further requirement that the composition further <b>comprises an effective amount of a component that assists in the preservation of the composition.</b></p> <p><i>See, e.g., '337 patent, col. 3, lines 49-61; col. 9, lines 43-45.</i></p>	<p>Claim 10 includes all the limitations of claim 6 with the further requirement that the composition further <b>comprises an effective amount of a preservative.</b></p> <p><i>See, e.g., '337 patent, col. 9, lines 43-45.</i></p>

**'834 patent**

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
<b>Claim 1</b>			
1. A therapeutically effective aqueous ophthalmic composition comprising:	<p>The claim requires a therapeutically effective aqueous ophthalmic composition.</p> <p><i>See, e.g.</i>, '834 patent file history, Reply to office action, dated Mar. 24, 2003.</p>	<p>The claim requires a therapeutically effective aqueous ophthalmic composition.</p> <p><i>See, e.g.</i>, '834 patent file history, Reply to office action, dated Mar. 24, 2003.</p>	
up to about 0.15% (w/v) of 5-bromo-6-(2-imidazolin-2-ylamino) quinoxaline tartrate,	<p>The claimed composition comprises up to approximately 0.15% brimonidine tartrate.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '834 patent, Fig. 1; col. 1, lines 33-53; col. 2, lines</p>	<p>The claimed composition comprises up to approximately 0.15% brimonidine tartrate.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	<p>A water-based formulation containing between 0% and about 0.15% (w/v) of brimonidine tartrate for ophthalmic administration that is demonstrated to provide a therapeutic benefit to a patient to whom the formulation is administered.</p> <p><i>See, e.g.</i>, '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Col. 3:23-29, Col. 10:65-Col.11:3.</p>

<sup>7</sup> Because the claim language itself is clear and unambiguous, no resort to the specification and prosecution history is necessary, therefore, the best evidence that the plain and ordinary meaning of the claim terms controls is the claims themselves. For brevity, citation to the claim language itself will not be repeated each time as the claim language is provided in Column 1.

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
	48-52; col. 3, lines 23-36; col. 6, lines 8-16; col. 11, lines 1-6; Example 2; Table IV; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018.		
the composition having a pH of about 7.0 or greater,	<p>The claimed composition has a pH of approximately 7.0 or greater.</p> <p>The ordinary meaning of the term "about" is "approximately." <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '834 patent, Figure 1; col. 4, lines 22-33; col. 11, lines 1-6; Example 2; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018.</p>	<p>The claimed composition has a pH of approximately 7.0 or greater.</p> <p>The ordinary meaning of the term "about" is "approximately." <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	<p>The therapeutically effective formulation referred to above has a pH of 7.0 or greater within measurement tolerances. In no event can the claim cover a formulation having a pH of 6.8 or below.</p> <p><b>pH:</b> pH is a value taken to represent the acidity or alkalinity of an aqueous solution; it is defined as the logarithm of the reciprocal of the hydrogen-ion concentration of a solution:</p> $\text{pH} = \log_{10} 1/\text{[H}^+\text{]}$ <p>Because the pH scale is logarithmic, the intervals are exponential and thus represent far greater differences in concentration than the values themselves seem to indicate. (Hawley's Condensed Chemical Dictionary, 853- 54 (2001)).</p>

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
			<p><i>See, e.g.,</i> '834 patent file history, Reply to Office Action, dated Mar. 24, 2003.</p> <p>During prosecution, applicants disclaimed any pH at or below 6.8 with regard to the - "having a pH of about 7.0 or greater" claim limitation.</p> <p>In order to overcome a § 103(a) reference to Burke (U.S. Patent No. 5,215,991) and Beck (U.S. Patent No. 6,358,935), applicant argued that "the present invention is the result of the <i>surprising finding</i> that increasing the pH of a brimonidine solution to a pH of greater than about 7.0 leads to similar efficacy at a 25% lower concentration (from 0.2% (w/v) to about 0.15% (w/v) or less) <i>than is seen in a brimonidine solution at a pH of about 6.6-6.8.</i>"</p> <p><i>See also</i> Preliminary Amendment dated Nov. 11, 2002, adding for the first time the limitation "the composition having a pH of about 7.0 or greater"; the specification as filed</p>

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
			<p>referred to a pH of about 7 or greater. The use of an additional decimal place (i.e., 7.0) in the claim signifies to one skilled in the art that the patentee intends precision to at least one decimal place.</p> <p>This interpretation is confirmed in the specification in Figure 1, Figure 1 presents solubility data for tests on formulations containing 0.2% brimonidine tartrate. The data shown in Figure 1 is taken from Table IV but omits (and thereby disclaims) all data points for pH values of below 7.0. Specifically excluded are 6.93, 6.68, and 6.67. <i>See also</i> Col. 1:32-45; <i>See Pall Corp. v. Micron Separations, Inc.</i>, 66 F.3d 1211, 1217 (Fed. Cir. 1995).</p> <p><i>See also Allergan, Inc. v. Alcon Inc.</i>, C.A. No. 04-968, 2005 U.S. Dist. LEXIS 32436, at *11 (D. Del. Dec. 8, 2005) ("According to the specification, the claimed compositions enhance the effectiveness of brimonidine tartrate (and other alpha-2-adrenergic agonist components) by</p>

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
			increasing its apparent water solubility <i>at pHs higher than neutral, or 7.0</i> ") (emphasis added).
and the 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate being soluble in the composition at about 21° C.	<p>The brimonidine tartrate is soluble in the composition at approximately 21° C.</p> <p>The ordinary meaning of the term "about" is "approximately." <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '834 patent, Fig. 1; Example 2; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018.</p>	<p>The brimonidine tartrate is soluble in the composition at approximately 21° C.</p> <p>The ordinary meaning of the term "about" is "approximately." <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	The brimonidine tartrate is soluble in the therapeutically effective formulation referred to above at a temperature of about 21 ° C.
<b>Claim 2</b>			
2. The composition of claim 1 which includes up to 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate.	Claim 2 includes all the limitations of claim 1, with the additional requirement that the composition includes up to 0.15% brimonidine tartrate.	Claim 2 includes all the limitations of claim 1, with the additional requirement that the composition includes up to 0.15% brimonidine tartrate.	The composition of claim 1, wherein the composition includes up to and no more than 0.15% (w/v) of brimonidine tartrate. <i>See</i> claim 1.

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
	<i>See citations for claim 1.</i>		
<b>Claim 3</b>			
3. The composition of claim 1 which includes about 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate.	<p>Claim 3 includes all the limitations of claim 1, with the additional requirement that the composition includes approximately 0.15% brimonidine tartrate.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See also</i> citations for claim 1.</p>	<p>Claim 3 includes all the limitations of claim 1, with the additional requirement that the composition includes approximately 0.15% brimonidine tartrate.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	<p>The composition of claim 1 which includes about 0.15% (w/v) of brimonidine tartrate.</p> <p><i>See</i> claim 1.</p>
<b>Claim 4</b>			
4. The composition of claim 1 which included 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate.	<p>Claim 4 includes all the limitations of claim 1, with the additional requirement that the composition includes 0.15% brimonidine tartrate.</p> <p><i>See</i> citations for claim 1.</p>	<p>Claim 4 includes all the limitations of claim 1, with the additional requirement that the composition includes 0.15% brimonidine tartrate.</p>	<p>The composition of claim 1 which includes 0.15% (w/v) of brimonidine tartrate.</p> <p><i>See</i> claims 1, 2.</p>

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
<b>Claim 5</b>			
5. The composition of claim 1 having a pH of 7.0 or greater.	Agreed-upon construction: Claim 5 includes all the limitations of claim 1, with the additional requirement that the pH of the composition is 7.0 or greater.		Not applicable to Exela.
<b>Claim 6</b>			
6. The composition of claim 1 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition.	Claim 6 includes all the limitations of claim 1 and further requires that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition.  <i>See, e.g.</i> , citations for claim 1; '834 patent, col. 3, lines 49-61; col. 9, line 23 – col. 10, line 44; Example 2.	Claim 6 includes all the limitations of claim 1 and further requires that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition.	The composition of claim 1, which further comprises a preservative selected from a group consisting of either: (1) oxidative preservative components, for example oxy-chloro components; or (2) quaternary ammonium compounds, in an amount effective to at least assist in preserving the composition.  <i>See claim 1; Col. 9:54-58.</i>
<b>Claim 7</b>			
7. The composition of claim 6 wherein the oxy-chloro component comprises a chlorite component.	Agreed-upon construction: Claim 7 includes all the limitations of claim 1 and further requires that the oxy-chloro component comprises a chlorite component.		Not applicable to Exela.
<b>Claim 8</b>			
8. The composition of claim 1 which is substantially free of anionic cellulosic derivatives.	Claim 8 includes all the limitations of claim 1 and further requires that the composition be substantially free of anionic cellulosic derivatives.	Not applicable. Allergan did not assert this claim against Apotex.	The composition of claim 1, wherein the composition includes anionic cellulose derivatives, which include metal carboxymethylcelluloses, metal

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
	<p><i>See, e.g.</i>, citations for claim 1; '834 patent, col. 6, lines 17-18; cols. 6-8; '834 patent file history, preliminary amendment</p>		<p>carboxymethylhydroxyethylcelluloses, and hydroxypropylmethylcelluloses and derivatives thereof, in an amount from 0.1 % to about 30% (w/v).</p> <p><i>See</i> claim 1.</p> <p><b>Anionic cellulosic derivatives:</b> Col 8:26-31.</p> <p><b>Substantially free:</b> Col. 3:23-35; Col. 8:61-Col. 9:6.</p> <p>The patent does not define or describe any therapeutically effective formulation of brimonidine tartrate having the properties described in claim 1 and that is “substantially free” of anionic cellulosic derivatives. Accordingly, to the extent this limitation is susceptible to definition, the range described should be applied.</p>

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
<b>Claim 9</b>			
9. The composition of claim 1 which is substantially free of carboxymethyl cellulose.	<p>Claim 9 includes all the limitations of claim 1 and further requires that the composition be substantially free of carboxymethyl cellulose.</p> <p><i>See</i> citations for claims 1 and 8.</p>	Not applicable to Apotex.	<p>The composition of claim 1, wherein the composition contains carboxymethyl cellulose in an amount from 0.1 % to about 30% (w/v).</p> <p><i>See</i> claim 1, 8.</p>
<b>Claim 10</b>			
10. A therapeutically effective aqueous ophthalmic composition comprising:	<p>The claim requires a therapeutically effective aqueous ophthalmic composition.</p> <p><i>See, e.g.</i>, '834 patent file history, Reply to office action, dated Mar. 24, 2003.</p>	<p>The claim requires a therapeutically effective aqueous ophthalmic composition.</p> <p><i>See, e.g.</i>, '834 patent file history, Reply to office action, dated Mar. 24, 2003.</p>	<p>A water-based formulation containing between 0% and about 0.15% (w/v) of a component selected from the group consisting of:</p>
up to about 0.15% (w/v) of a component selected from the group consisting of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, salts of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, esters of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline and mixtures thereof,	<p>The claimed composition comprises up to approximately 0.15% brimonidine, salts of brimonidine, esters of brimonidine, or mixtures of the foregoing.</p> <p>The ordinary meaning of the term "about" is "approximately." <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-</p>	<p>The claimed composition comprises up to approximately 0.15% brimonidine, salts of brimonidine, esters of brimonidine, or mixtures of the foregoing.</p> <p>The ordinary meaning of the term "about" is "approximately." <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-</p>	<p>brimonidine; salts of brimonidine; esters of brimonidine; or mixtures thereof, for ophthalmic administration that is demonstrated to provide a therapeutic benefit to a patient to whom the formulation is administered.</p> <p><i>See</i> claim 1.</p>

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
	<p>968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.,</i> '834 patent, Fig. 1; col. 1, lines 33-53; col. 2, lines 48-52; col. 3, lines 23-36; col. 6, lines 8-16; col. 11, lines 1-6; Example 2; Table IV; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018.</p>	<p>968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	
<p>the composition having a pH of about 7.0 or greater,</p>	<p>The claimed composition has a pH of approximately 7.0 or greater.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.,</i> '834 patent, Figure 1; col. 4, lines 22-33; col. 11, lines</p>	<p>The claimed composition has a pH of approximately 7.0 or greater.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	<p>The therapeutically effective formulation referred to in claim 10 having a pH of 7.0 or greater within measurement tolerances. In no event can the claim cover a formulation having a pH of 6.8 or below.</p> <p><i>See</i> claim 1.</p>

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
	1-6; Example 2; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018.		
and the component being soluble in the composition at about 21° C.	<p>The brimonidine component is soluble in the composition at approximately 21° C.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See, e.g.</i>, '834 patent, Fig. 1; Example 2; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018.</p>	<p>The brimonidine component is soluble in the composition at approximately 21° C.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharm. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p>	<p>The brimonidine tartrate is soluble in the therapeutically effective formulation referred to above at a temperature of about 21 ° C.</p> <p><i>See</i> claim 1.</p>
<b>Claim 11</b>			

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
11. The composition of claim 10 which includes up to 0.15% (w/v) of the component.	<p>Claim 11 includes all the limitations of claim 10, with the additional requirement that the composition includes up to 0.15% of the brimonidine component.</p> <p><i>See</i> citations for claim 10.</p>	Claim 11 includes all the limitations of claim 10, with the additional requirement that the composition includes up to 0.15% of the brimonidine component.	<p>The composition of claim 10, wherein the composition includes up to and no more than 0.15% (w/v) of the component.</p> <p><i>See</i> claims 2, 10.</p>
<b>Claim 12</b>			
12. The composition of claim 10 which includes about 0.15% (w/v) of the component	<p>Claim 12 includes all the limitations of claim 10, with the additional requirement that the composition includes approximately 0.15% of the brimonidine component.</p> <p>The ordinary meaning of the term “about” is “approximately.” <i>See Merck &amp; Co., Inc. v. Teva Pharms. USA, Inc.</i>, 395 F.3d 1364, 1377 (Fed. Cir. 2005); <i>Allergan Inc. v. Alcon Inc.</i>, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).</p> <p><i>See</i> citations for claim 10.</p>	Claim 12 includes all the limitations of claim 10, with the additional requirement that the composition includes approximately 0.15% of the brimonidine component.	<p>The composition of claim 10 which includes about 0.15% (w/v) of the component.</p> <p><i>See</i> claims 3, 10.</p>
<b>Claim 13</b>			

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
13. The composition of claim 10 which includes 0.15% (w/v) of the component	Claim 13 includes all the limitations of claim 10, with the additional requirement that the composition includes 0.15% of the brimonidine component.  <i>See citations for claim 10.</i>	Claim 13 includes all the limitations of claim 10, with the additional requirement that the composition includes 0.15% of the brimonidine component.	The composition of claim 10 which includes 0.15% (w/v) of the component.  <i>See claims 4, 10.</i>
<b>Claim 14</b>			
14. The composition of claim 10 having a pH of 7.0 or greater.	Agreed-upon construction: Claim 14 includes all the limitations of claim 10, with the additional requirement that the pH of the composition is 7.0 or greater.		Not applicable.
<b>Claim 15</b>			
15. The composition of claim 10, which further comprises an oxy-chloro component in an amount effective to at least assist in preserving the composition.	Agreed-upon construction: Claim 15 includes all the limitations of claim 10, and further requires that the composition further comprises an oxy-chloro component in an amount effective to assist in preserving the composition.		Not applicable.
<b>Claim 16</b>			
16. The composition of claim 15 wherein the oxy-chloro component comprises a chlorite component.	Agreed-upon to construction: Claim 16 includes all the limitations of claim 15, with the additional requirement that the oxy-chloro component comprises a chlorite component.		Not applicable.
<b>Claim 17</b>			
17. The composition of claim 10 which is substantially free of anionic cellulosic derivatives.	Claim 17 includes all the limitations of claim 10 and further requires that the composition be substantially free of anionic cellulosic derivatives.	Not applicable.	The composition of claim 10, wherein the composition includes anionic cellulose derivatives, which include metal carboxymethyl-celluloses, metal

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	<p><i>See</i> citations for claim 10; '834 patent, col. 6, lines 17-18; cols. 6-8; '834 patent file history, preliminary amendment</p>		<p>carboxymethylhydroxyethylcelluloses, and hydroxypropylmethylcelluloses and derivatives thereof, in an amount from 0.1 % to about 30% (w/v).</p>
<b>Claim 18</b>			
18. The composition of claim 10 which is substantially free of carboxymethyl cellulose.	<p>Claim 18 includes all the limitations of claim 10 and further requires that the composition be substantially free of carboxymethyl cellulose.</p>	<p>Not applicable.</p>	<p>The composition of claim 10, wherein the composition contains carboxymethyl cellulose in an amount from 0.1% to about 30% (w/v).</p>
<p><i>See</i> claims 8, 10.</p>			
<b>Claim 20</b>			
20. The composition of claim 10 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition.	<p>Claim 20 includes all the limitations of claim 10, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition.</p>	<p>Claim 20 includes all the limitations of claim 10, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition.</p>	<p>The composition of claim 10 which further comprises a preservative selected from a group consisting of either: (1) oxidative preservative components, for example oxy-chloro components; or (2) quaternary ammonium compounds, in an amount effective to at least assist in preserving the composition.</p>
<p><i>See</i> claims 6, 10.</p>			

Asserted Claim of '834 Patent	Allergan's Proposed Construction <sup>7</sup>	Apotex's Proposed Construction	Exela's Proposed Construction
	claim 10; '834 patent, col. 3, lines 49-61; col. 9, line 23 – col. 10, line 44; Example 2.		
<b>Claim 22</b>			
22. The composition of claim 20 in which the preservative comprises a oxy-chloro component.	Agreed -upon construction: Claim 22 includes all the limitations of claim 20, with the additional requirement that the preservative comprises an oxy-chloro component.		Not applicable.

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